

Appl. No. 10/699,351  
Atty. Docket No. 9129L  
Reply to Office Action of March 8, 2006  
Customer No. 27,752

### REMARKS

Claims 1-78 are pending in the present application. The Applicants appreciate the Examiner's correction of the claim numbering based on 78 total original claims. The Examiner has withdrawn the previous restriction and election requirement but has again restricted prosecution of the application stating that the application contains claims directed to patentably distinct inventions. The Examiner states that claims 1-36 and 71 (Group I), claims 37-48 (Group), claims 49-58 and 72 (Group III), and claims 59-70 and 73-79 (should read 73-78, Group IV) are drawn to separate, unrelated inventions, that the searches for each group are not co-extensive and would result in undue burden to the Examiner.

In addition, the Examiner states that claims 1, 13, 25, 31, 37, 43, 54, 59, 65, 68, 71, 72, 73, and 78 are drawn in Markush format and encompass multiple and patentably distinct inventions. Thus, the Examiner requires election of a single species for prosecution on the merits.

The Applicants respectfully traverse the restriction and election requirements. The Applicants assert that if the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though the Examiner is of the viewpoint that the claims should otherwise be restricted. See MPEP 803. The Examiner states that groups I and II are related as product and process of use, groups I and III are related as product and process of use, groups IV and I are related as product and process of use, groups II and III are related as product and process of use, groups II and IV are related as product and process of use, and groups III and IV are related as product and process of use.

The Applicants assert that there would not be an undue burden as the searches would be coextensive.

Further, in explaining the restriction requirement with respect to the relationships of the various groups of claims, the Examiner repeatedly states that "increasing the viscosity in the gastrointestinal tract can be employed by another method, adding oats to the diet" and citing a British Journal of Nutrition article, by McDonald et al. (hereinafter referred to as "McDonald").

The Applicants disagree with the Examiner's assessment and use of McDonald to attempt to show that the Applicants invention, with respect to all groups of claims set out by the Examiner,

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could have been employed by another method. McDonald does not show that the Applicants' methods of increasing viscosity could be achieved by adding oats to one's diet. Oats are mentioned only twice in McDonald, and a lipase inhibitor, as recited in the Applicants' claims, is not mentioned at all.

The first disclosure of oats is in the first sentence of the abstract which states: "Sources of viscous soluble fibre, such as barley and oats, have often been included in the weaning diet of the pig to accelerate development of the large intestine." Oats are not cited here for increasing viscosity in the gastrointestinal tract. The second disclosure of oats is at page 495, the second full paragraph where it states: "Some studies have tested diets containing fibres that are commonly viscous and fermentable (e.g. oats), but extrapolation of results is difficult because the intestinal viscosity of these diets and intestinal samples *was not measured*." Thus, McDonald specifically notes that there is nothing that specifically states that oats increase the viscosity in the gastrointestinal tract. Viscosity was not even measured in the cited experiments.

In addition McDonald used carboxymethylcellulose (CMC) in the experiments, and specifically did NOT use any grains because they did not want fermentation occurring. However, McDonald found that increased levels of CMC resulted in detrimental physical effects to the pigs' small intestines (atrophy), as well as diarrhea and *E. coli* infection in all pigs fed the higher levels of CMC. Thus, McDonald found that although the CMC increased the viscosity of the contents of the digestive tract, detrimental health effects occurred, including diarrhea and *E. coli* infection.

McDonald also discloses that others have used other compounds such as pectin, barley, and guar gum, for various purposes and with various results – some desirable, some detrimental. Thus, not even all compounds that increase viscosity in the digestive tract produce the same results or physical effect (such as *treating* gastrointestinal distress versus *creating* it).

In the conclusion, McDonald specifically states that the interplay between viscosity, fermentation, and microflora is extremely complex and is undoubtedly altered by the type of fermentative or viscous compounds involved, amongst many other factors.

Thus, there is no indication in McDonald that adding oats to one's diet would appropriately or beneficially increase the viscosity in the digestive tract, as the Examiner asserts.

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Thus, there is no indication in McDonald that the Applicants' compositions and methods with respect to increased viscosity in the gastrointestinal tract could be achieved by other methods. Simply adding oats to ones' diet would not result in the Applicants' composition, methods, or kits. Therefore, because McDonald does not disclose that increased viscosity in the digestive tract would be achieved by oats, the restriction, as reasoned by the Examiner, is not proper. The Applicants respectfully request withdrawal of the restriction requirement and examination of all claims.

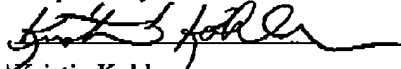
However, in response to the election requirement, the Applicants provisionally elect, with traverse, the claims of Group I, which include claims 1-36 and 71.

In addition, as elected in the Applicants' previous response, the Applicants further elect a stiffening agent of R-COOR' including fatty acids (components in which R' is hydrogen), i.e. R-COOH, and the salts of the fatty acids. Examples include stearic acid, and its salts, for example its calcium salt, calcium stearate. The Applicants further elect lipase inhibitors lipstatin and tetrahydrolipstatin (known also as (S)-1-[(2S,3S)-3-hexyl-4-oxooxetan-2-yl]methyl]dodecyl N-formyl-L-leucinate) and their derivatives.

The Applicants therefore respectfully request that Examiner reconsider the Restriction Requirement and proceed to examination of all claims in the application on the merits. If the Examiner believes that personal contact would be beneficial for disposition of the present application, the Examiner is respectfully requested to contact the undersigned.

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Respectfully submitted,



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